

Policy Name:	Impavido (miltefosine)	Policy #:	2550P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Impavido.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Impavido under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of one of the following
 - Visceral leishmaniasis due to *Leishmania donovani*
 - Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*
 - Mucosal leishmaniasis due to *Leishmania braziliensis*
- 1.2 Prescribed by or in consultation with an Infectious Disease Specialist
- 1.3 Age 12 years or older weighing at least 30kg
- 1.4 Documented failure, intolerance, or contraindication to Amphotericin B

2. Exclusion Criteria

- 2.1 Pregnancy
- 2.2 Sjogren-Larsson Syndrome

3. Approval Period

- 3.1 Approve 28-day treatment regimen within 6 months coverage duration

CPT Codes

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HCPCS Codes

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References

1. Impavido (miltefosine) [prescribing information]. Orlando, FL: Profounda Inc; May 2021.
2. Aronson N, Herwaldt BL, Libman M, et al. Diagnosis and Treatment of Leishmaniasis: Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH). *Am J Trop Med Hyg.* 2017;96(1):24-45.

Created Date: 12/07/16

Effective Date: 07/01/24

Posted to Website: 01/01/22

Revision Date: 02/07/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.